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EXAMINER

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RONALD R SANTUCCI
PITNEY HARDIN KIPP & SZUCH
711 THIRD AVENUE 20TH FLOOR
NEW YORK NY 10017

SQUAYA, T	
ART UNIT	PAPER NUMBER

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/508,238

Applicant(s)

Berghof et al

Examiner

Jehanne Souaya

Group Art Unit

1655

☒ Responsive to communication(s) filed on May 8, 2000☐ This action is **FINAL**.☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims☒ Claim(s) 1-18 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.☒ Claim(s) 1-18 is/are rejected.☐ Claim(s) _____ is/are objected to.☐ Claims _____ are subject to restriction or election requirement.**Application Papers**☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.☐ The drawing(s) filed on _____ is/are objected to by the Examiner.☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.☐ The specification is objected to by the Examiner.☐ The oath or declaration is objected to by the Examiner.**Priority under 35 U.S.C. § 119**☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been☐ received.☐ received in Application No. (Series Code/Serial Number) _____.☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).**Attachment(s)**☒ Notice of References Cited, PTO-892☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____☐ Interview Summary, PTO-413☐ Notice of Draftsperson's Patent Drawing Review, PTO-948☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

.Claim Rejections - 35 USC § 101

1. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 12-18 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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The claims are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with idiomatic errors. The claims should be rewritten to conform to claim language used in US practice. For instance, all claims lack an article at the beginning of the claims, such that the claims should recite "A nucleic acid ..." or "A kit...". Furthermore, the claims are replete with terms lacking antecedent basis.

Claims 2 and 3 are indefinite in the recitation of "namely" as it is unclear whether this language is meant to further limit claim 1 in the alternative. That is, does the limitation of claim 2 read "a nucleic acid molecule having a shortened sequence compared to claim 1 *or* the sequence of the region or in the region of the nucleotide positions 12-131. The metes and bounds of the claim are unclear in that it cannot be determined how the term further limits the claim. nucleic acid would look like were it "derived" from another nucleic acid.

Claim 9 is indefinite in the recitation of the phrase "building blocks known per se as probes and/or primers" as it is unclear how this claim further limits the invention. The term "building blocks" in relation to probes and primers is not an art recognized term and it cannot be determined from the claim language what limitations should be attributed to claim 9. It is further unclear how the nucleic acid molecule in claim 9 is "modified".

Claims 12-18 provide for the use of a set of nucleic acids, but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is

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intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 5 and 9 are rejected under 35 U.S.C. 102(a) as being anticipated by Accession number U79958, October 6, 1997.

The claims as written encompass any nucleic acid molecule such that ten consecutive nucleotides of its sequence are identical to a nucleic acid molecule of SEQ ID NOS 1-5, or fragments of SEQ ID NO 1, or 9 of 10 consecutive or 8 of 10 consecutive nucleotides from SEQ ID NOS 1-5 or is 90% homologous to SEQ DI NOS 1-5 or fragments of SEQ ID NO 1. Accession number U79958 teaches a sequence that possesses at least 10 consecutive sequences of SEQ ID NO 4.

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6. Claims 5 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Accession number Y00432, March 18, 1991, or Accession number X15400 referenced in Nature, vol. 340, pp 531-536, 1989.

The claims as written encompass any nucleic acid molecule such that ten consecutive nucleotides of its sequence are identical to a nucleic acid molecule of SEQ ID NOS 1-5, or fragments of SEQ ID NO 1, or 9 of 10 consecutive or 8 of 10 consecutive nucleotides from SEQ ID NOS 1-5 or is 90% homologous to SEQ ID NOS 1-5 or fragments of SEQ ID NO 1. Accession number X15400 teaches a sequence that possesses at least 10 consecutive sequences of SEQ ID NO 3. Accession number Y00432 a nucleic acid molecule that contains 20 consecutive nucleotides that are identical to SEQ ID NO 2.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor

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and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Kur et al (Acta Microbiologica Polonica, 1995, vol. 44, pp 111-117) and Jannes et al, (WO 96/00298) and Hogen (US patent 5,714,321) in view of Accession number Y00432, March 18, 1991, or Accession number X15400 referenced in Nature, vol. 340, pp 531-536, 1989 or Accession number U79958, October 6, 1997.

The claims are drawn to nucleic acids that can be used to detect different species of *Pseudomonas*. Kur teaches the identification of *Pseudomonas aeruginosa* by detecting PCR amplified Ribosomal DNA Spacer polymorphisms. Kur teaches that *Pseudomonas aeruginosa* is an opportunistic pathogen in humans and that because of its resistance to antibiotics, it has been isolated frequently in sever nosocomial infections, especially from immunocompromised patients (see p 111). Therefore, Kur provides the ordinary artisan with motivation to identify *Pseudomonas aeruginosa* and teaches doing so with PCR primers that can exclusively detect this species.

Jannes teaches an invention that detects and identifies at least one or several organisms in a sample by amplifying the 16S-23S rRNA spacer region of the organism and using species specific probes to differentiate between organisms (see abstract). Jannes specifically teaches

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providing probes for the identification of groups or species of different organisms including *Pseudomonas* species (p. 3).

It should be noted that the state of the art was very high at the time the invention was filed to construct probes and primers for the detection and differentiation of different strains of closely related bacteria and fungi. For example, a number of US patents were given to Hogan et al (5,714,321 is enclosed) to methods and nucleic acids for detecting and differentiating different strains of bacteria. A large number of references were available, at the time the invention was made, that taught the ordinary artisan how to align sequences of bacteria to determine regions of similarity and variability to detect and differentiate different strains of bacteria. As the species of and strains of *Pseudomonas* were known and available in the art at the time of filing, it would have been *prima facie* obvious to one of ordinary skill to align the sequences of different species of *Pseudomonas* for the purpose of providing nucleic acids for detecting and differentiating different species of *Pseudomonas*. Although neither Kur nor Jannes teach the exact nucleic acid molecules "consisting" of the SEQ ID Nos of the claimed invention, Kur and Jannes provide motivation for the skilled artisan to construct these sequences and the sequences encompassed by the broadly claimed invention. Therefore it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to construct sequences to detect different species of *Pseudomonas* because Kur and Jannes teach of a need to do so and Hogan teaches how to construct nucleic acid molecules for the purpose of detecting different closely related species of bacteria.

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A showing of unexpected results, however, could overcome this rejection. Evidence that certain primers or probes worked better than others would constitute unexpected results, and therefore, those *specific* probes and primers would be patentable over the disclosure of Kur and Jannes and the general high state of the art.

9. No claims are allowable.


10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Souaya whose telephone number is (703)308-6565. The examiner can normally be reached Monday-Thursday from 7:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.


W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600

3/12/01


Jehanne Souaya
Patent examiner
March 7, 2001